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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,595

02/23/2007

Christopher Speirs

SPEI3003/ESS

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ALEXANDRIA, VA 22314-1176

EXAMINER

YU, HONG

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,595	<b>Applicant(s)</b> SPEIRS ET AL.	
	<b>Examiner</b> HONG YU	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2,4,6-12,14,18,20,24-26,28-30,32-34,36,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4,8-12,20,24-26,28-30,32-34,36,40 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/13/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Claims 2, 4, 6-12, 14, 18, 20, 24-26, 28-30, 32-34, 36, 40, and 41 are pending, claims 1, 3, 5, 13, 15-17, 19, 21-23, 27, 31, 35, 37-39 are canceled in this application. This application is a national stage entry of PCT/GB04/05263, filled on 12/15/2004). This application claims foreign priority to GB 0329851.0, filed on 12/23/2003) in Great Britain and to GB 0329854.4, filed on 12/23/2003) in Great Britain.

***Election/Restrictions***

1. During a telephone conversation with Mr. Eric Spector on species election, on 07/27/2009, a provisional election was made without traverse to prosecute the species of "from about 80% to about 98% of particles have a diameter between the range of about 800 to about 1500  $\mu\text{m}$ ", claim 4. Affirmation of this election must be made by applicants in replying to this Office action. Claims 6 and 7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

2. Claims **2, 4, 8-12, 14, 18, 20, 24-26, 28-30, 32-34, 36, 40, and 41** will presently be examined to the extent they read on the elected subject matter of record.

***Specification***

3. The misspelling has been noted in this application: erythropoietin is spelled as "erythropoetin". Appropriate correction is required.

***Claim Objections***

4. Claims 12 and 34 are objected to because of the following informalities: erythropoietin is spelled as "erythropoetin. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. ***Claims 8-10, 14, 18, 20, 24, 26, 28-30, 32, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Speirs (US 5,834,021).***

7. Speirs meets all of the limitations of the claim 40. Speirs teaches a preparation of pellets comprising: a) mixing water with component composition; b) extruding paste to form extrudate; c) spheronizing the extrudate; d) drying the sphere pellets (column 5, line 1-8).

8. Speirs meets all of the limitations of the claims 8-10, 14, 32, and 41. Speirs teaches the pellet composition comprising 5 to 20% by weight of the composition of prednisolone metasulphobenzoate (column 4, line 58-60). The range of the amount of prednisolone metasulphobenzoate in the reference is within that of the amount of prednisolone metasulphobenzoate in the instant claims, thus, anticipates the range of the amount of prednisolone metasulphobenzoate in the instant claims.

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9. Speirs meets all of the limitations of the claims 18, 20, 24, 26, and 28-30.

Speirs teaches the pellet composition further comprising 10 to 30% by weight of the composition of croscarmellose sodium (column 4, line 48-57 and example 10), 40% by weight of the composition of microcrystalline cellulose (example 1), and 50% by weight of the composition of lactose (example 1). Since the range of the weight of lactose in the instant claim is **about 35% to about 45%** by weight of the composition, 50% by weight of the composition of lactose disclosed in reference can be included in range of the **about 35% to about 45%** with 20% variable. The ranges of the amounts of croscarmellose sodium, microcrystalline cellulose, and lactose in the reference are within those of the amounts of croscarmellose sodium, microcrystalline cellulose, and lactose in the instant claims, thus, anticipate the ranges of the amounts of croscarmellose sodium, microcrystalline cellulose, and lactose in the instant claims.

**10. Claims 8-12, 18, 24, 26, 28, 29, 32-34, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al. (US 2003/0180352 A1).**

11. Patel et al. meet all of the limitations of the claim 40. Patel et al. teach a preparation of solid carrier comprising: a) mixing solvent (water) with component composition (paragraphs 255 and 312); b) extruding paste to form extrudate (paragraphs 312 and 323-326); c) spheronizing the extrudate (paragraphs 327-328); d) drying the sphere pellets (paragraph 312).

12. Patel et al. meet all of the limitations of the claims 8-12, 14, and 32-34. Patel et al. teach the pellet composition comprising active agent which can be

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metronidazole (paragraph 85), prednisolone (paragraph 90), and erythropoietin (paragraph 102).

13. Patel et al meet all of the limitations of the claims 18, 24, 26, 28, and 29. Patel et al. teach the pellet composition further comprising croscarmellose sodium (paragraph 248) and 5 to 95% by weight of the composition of microcrystalline cellulose and/or lactose (paragraph 248). The range of the amount of prednisolone metasulphobenzoate in the reference is within that of the amount of prednisolone metasulphobenzoate in the instant claims, thus, anticipates the range of the amount of prednisolone metasulphobenzoate in the instant claims.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

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35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**16. Claims 2, 4, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs (US 5,834,021) in view of Patel et al. (US 2003/0180352 A1) and Wolozin (US 6,472,421 B1).**

**17. Applicant's claims**

18. The instant claims 2, 4, and 36 recite preparation of pellets which comprising from about 180% to about 190% by weight of component composition of water and lactose monohydrate with spheronizing step processed with a 70 cm plate rotating at 200 to 1000 rpm. From about 80% to about 98% of dried pellets have a diameter from about 800 to about 1500  $\mu\text{m}$ .

***Determination of the Scope and Content of the Prior Art***  
***(MPEP 2141.01)***

19. The teachings of Speirs are discussed above and applied in the same manner.

***Ascertainment of the Difference between Scope of the Prior Art and the Claims***  
***MPEP 2141.02)***

20. Speirs does not specify the amount of water in the preparation as 180% to about 190% by weight of component composition.

21. Speirs does not specify spheronizing the extrudate with a 70 cm plate rotating at 200 to 1000 rpm, but specifies spheronizing the extrudate with a 20 cm plate rotating at about 1000 rpm.

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22. Speirs does not specify lactose monohydrate in the composition, but specifies lactose in the composition.

23. This deficiency is cured by Wolozin who teaches that lactose can be lactose monohydrate and lactose anhydrous (column 9, line 40 and 41).

24. Speirs does not specify from about 80% to about 98% of dried pellets having a diameter from about 800 to about 1500  $\mu\text{m}$ , but specifies the pellets having a diameter in the range 1000-1400  $\mu\text{m}$ .

***Finding of Prima Facie Obviousness Rational and Motivation***

***(MPEP 2142-2143)***

25. Speirs does not specify from about 80% to about 98% of dried pellets having a diameter from about 800 to about 1500  $\mu\text{m}$ , but specifies the pellets having a diameter in the range 1000-1400  $\mu\text{m}$ . It is assumed that the **average** diameter is within the range of 1000-1400  $\mu\text{m}$  in the reference. Although the range of the average diameter in the reference is within the range of the diameter of from about 80% to 98% of the pellets in the instant claim, it is not certain that from 80% to 98% of the pellets in the reference have the diameters within the range of from 800 to about 1500  $\mu\text{m}$  which means which means the range of the diameter of the pellets in the reference overlaps that of the pellets in the instant claim. A prima facie case of obviousness exists when the range of a claimed diameter overlaps the range disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974). It is the normal desire of



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scientists or artisans to adjust what is already generally known provides the motivation to determine where in a disclosed diameter range is the optimum.

See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980)

("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

26. Speirs does not specify the amount of water in the preparation as 180% to about 190% by weight of component composition. Though Speirs does not expressly teach the amount of water in the preparation, as a result of the composition having the same components, prepared with the same process, and have same range of diameter as claimed is considered to necessarily have the same amount of water in the preparation, whether expressly recognized by Speirs or not. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph).

27. Speirs does not specify spheronizing the extrudate with a 70 cm plate rotating at 200 to 1000 rpm, but specifies spheronizing the extrudate with a 20 cm plate rotating at about 1000 rpm. The size of the plate in a spheronizing device is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have

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been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of size of plate would have been obvious at the time of Applicants' invention.

28. Although Speirs does not specify lactose monohydrate in the composition, but specifies lactose in the composition; Wolozin specify that lactose can be lactose monohydrate and lactose anhydrous. It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Speirs and Wolozin to specify lactose monohydrate as a component in the composition. Lactose monohydrate and lactose anhydrous are well known as two types of lactose to a person of ordinary skill in the art at the time of the invention. It is generally considered to be prime facie obvious to specify a component which is taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for specifying it flows from its having been used in the prior art, and from its being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the specifying a conventional component of a pharmaceutical composition.

### ***Correspondence***

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is

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(571)270-1328. The examiner can normally be reached on M-Th 8:50 am-6:50 pm.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HONG YU  
Examiner, Art Unit 1616

*/Mina Haghighatian/*  
Primary Examiner, Art Unit 1616

